

RECEIVED
CENTRAL FAX CENTER

JUL 27 2006

Serial No. 10/647,057

Docket No. 30296A-DIV1

Remarks:

Claims 1, 3-6, 9-11, 16-19 remain for consideration in this application, with claims 1, 6, 11, 16 and 18 being in independent format. The claims of group 2 were previously withdrawn pursuant to the restriction requirement.

Applicant's response to the restriction included a traverse on the grounds that MPEP 803.04 indicated that, despite the fact that different nucleotide sequences represent distinct inventions subject to restriction requirement, normally ten sequences represent a reasonable number of sequences for examination purposes. In the Action, it was noted that allowing ten sequences per application was not the normal practice. Applicant's acknowledge that different sequences are patentably distinct inventions subject to restriction, however, MPEP 803.04 clearly states that the normal office practice is to examine 10 sequences per application. The basis for such an argument regarding the treatment of nucleotide sequences for restriction purposes is found in MPEP 803.04, set forth below:

Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode< different proteins are structurally distinct chemical compounds*. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 *et seq.* Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the *>Director< has decided sua sponte to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten

Serial No. 10/647,057

Docket No. 30296A-DIV1

independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

In some *exceptional* cases, the complex nature of the claimed material, for example a protein amino acid sequence reciting three dimensional folds, may necessitate that the reasonable number of sequences to be selected be less than ten.

MPEP 803.04 (emphasis added)

Thus, Applicants renew their request to have additional sequences searched and the MPEP clearly supports Applicant's request.

This amendment also includes an amendment to the specification updating the status of the priority documents as requested by the Examiner.

Claims 1-11 and 16 were rejected under 35 U.S.C. §112, first paragraph, for a lack of written description and enablement regarding the homology and mutation claims. Applicants have amended the claims to require a minimum of at least 87% sequence homology for nucleotide sequences to fall under these claims. In support of claims for that level of homology, Applicants note that people of ordinary skill in the art of manipulating nucleotide sequences as well as the proteins encoded by such nucleotide sequences have a good idea of the potential outcomes of a wide variety of manipulations of the nucleotide or protein sequence. Such knowledge permits them to make substitutions or variations which have very little or no effect on the function of the sequence. Thus, it is likely that sequences having at least 87% sequence homology with a specifically disclosed sequence in the

Serial No. 10/647,057

Docket No. 30296A-DIV1

present application would exhibit similar function with those sequences having a higher degree of sequence homology with the disclosed sequences, up to and including the disclosed sequences themselves. Furthermore, one of ordinary skill in the art would be able to easily construct sequences having 87% sequence homology with one of the disclosed sequences and retain the desired function of the sequence, without undue experimentation. Accordingly, Applicants assert that these rejections have been overcome.

With specific respect to the enablement rejection, Applicants assert that the skill in the art of protein and nucleotide manipulation have greatly progressed since the Bowie et al. article in 1990 and the Houghten et al. article in 1986. Thus, the experimentation necessary to enable the full scope of the claims herein is not undue.

New claims 18 and 19 also satisfy the written description requirement for the same reasons. Applicants further note that claim 18 claims the nucleotide sequences that would encode an amino acid sequence that is a truncated form of SEQ ID No. 1, which is the protein encoded by the elected sequence of this application, namely SEQ ID No. 8. Additionally, the nucleotide sequence of claim 18 must encode a protein having at least 339 contiguous amino acids of SEQ ID No. 1. This claim is supported by the truncated peptides encoded by portions of the elected sequence.

Claims 1-11 and 16 were rejected under 35 U.S.C. §102(b) as being anticipated by Struck et al. (U.S. Patent No. 5,804,190). All of the claims now require at least 87% homology over a 1017 nucleotide length portion of SEQ ID No. 8. Struck does not teach or suggest such a homologous region and therefore cannot be said to anticipate or even obviate the present claims.

Serial No. 10/647,057

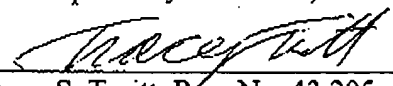
Docket No. 30296A-DIV1

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 50-2790.

Respectfully submitted,

By


Tracey S. Truitt, Reg. No. 43,205
ERICKSON & KLEYPAS, L.L.C.
800 W. 47th Street, Suite 401
Kansas City, Missouri 64112
816/753-6777
ATTORNEYS FOR APPLICANT(S)

Certificate of Facsimile Transmission

I hereby certify that this AMENDMENT AND RESPONSE along with the Petition for Extension of Time Under 37CFR 1.136 (3 month) for application Serial No. 10/647,057, filed August 22, 2003, are being filed by facsimile transmission to the United States Patent and Trademark Office at fax number (571) 273-8300 on July 27, 2006.

By


Tracey S. Truitt

7/27/06
(Date of Signature)